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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,043	02/17/2004	Elizabeth Bates	SF0977XB	1489

28008 7590 05/27/2010

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EXAMINER	
DAHLE, CHUN WU	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
05/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/780,043	BATES ET AL.	
	Examiner	Art Unit	
	CHUN DAHLE	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,18 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9, 18, and 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendments, filed on April 2, 2010, are acknowledged.

Claims 1-6, 8, 10-17, and 19-31have been canceled.
Claim 32-34 has been added.

Claims 7, 9, 18, and 32-34 are pending and currently under consideration.

2. This Office Action will be in response to applicant's arguments, filed on April 2, 2010.

The rejections of record can be found in the previous Office Actions, mailed on February 22, 2006, July 17, 2006, November 20, 2006, August 9, 2007, February 5, 2008, and August 14, 2008, March 31, 2009, and January 5, 2010.

3. In view of applicant's amendment to the claims, the prior rejection under 35 U.S.C. 112 second paragraph, against claims 7, 9, 18, and 25, has been withdrawn.

4. This is **a New Ground of Rejection** necessitated by applicant's amendment to the claims. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Newly added claims 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a *Written Description*, New Matter rejection.

The term "residues 1-210 of SEQ ID NO:6" as recited in newly added claims 32-34 are not supported by the original disclosure or claim as filed.

Applicant's amendment, filed on April 2, 2010, asserts that residues 1-210 of SEQ ID NO:6 represents the mature sequence and directs to support to page 7, original claim 2 and SEQ ID NOs: 5 and 6, and asserts that no new matter has been added.

However, the specification as filed does not provide sufficient written description of the above-mentioned "limitations". The specification does not provide sufficient support for "residues 1-210 of SEQ ID NO:6". The specification only discloses FDF03-S1 having the amino acid sequence of SEQ ID NO:6 consisting of 227 amino acid residues. The original claim 2 encompasses polypeptide including SEQ ID NO:6 comprising the amino acid sequence of the mature protein but does not recite residues 1-210.

The instant claims now recite "residues 1-210 of SEQ ID NO:6", which was not clearly disclosed in the specification. Therefore, the claims represent a departure from the specification and claims originally filed. Applicant's reliance on generic disclosure, e.g. mature protein, does not provide sufficient direction and guidance to the features currently claimed ("residues 1-210 of SEQ ID NO:6").

Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02, 2163.05-06 and 2173.05 (i).

6. This is **a New Ground of Rejection** necessitated by applicant's amendment to the claims. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 7, 9, 18, and newly added 32-34 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 7, 9, 18, and 32-34 are drawn to an antigen-antibody complex comprising an antibody or fragment thereof that specifically binds an FDF03-S1 polypeptide consisting of the amino acid sequence of SEQ ID NO:6 and said FDF03-S1.

The specification discloses that the FDF03-S1 polypeptide is found in activated monocytes and plays a role in regulation or development of hematopoietic cells including lymphoid cells, which affect immunological responses, e.g. antigen presentation and the resulting effector functions (e.g. see page 2 and 23).

Claims 7, 9, 18, and 32-34, as written, do not sufficiently distinguish over antigen-antibody complexes as they exist naturally, e.g autoantibodies against FDF03-S1 found in monocytes, which in turn, would form antigen-antibody complexs with the antigen in vivo, because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980).

The claims should be amended to indicate the hand of the inventor. Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 7, 9, 18, 25, and newly added claims 32-34 are rejected under 35 U.S.C. 102(a) as being anticipated by Adema et al. (WO 98/24906, cited in IDS filed 02/17/04) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586, reference listed on PTO-892 mailed on February 22, 2006) and Bendayan (J. Histochem. Cytochem. 1995; 43:881-886, reference listed on PTO-892 mailed on February 22, 2006) for reasons of record.

The prior Office Action states:

"Adema et al. teach an isolated polypeptide of SEQ ID NO:2 isolated from monocyte wherein SEQ ID NO:2 is 80.4% identical to the claimed polypeptide of SEQ ID NO:6 (see attached sequence alignment of record). Adema et al. further teach methods of making and using monoclonal antibodies using polypeptide having amino acid sequences of SEQ ID NO:2 as immunogen using techniques such as hybridoma and recombinant technology. Furthermore, Adema et al. teach that the antibody can be fragment such as Fab, Fv, and can be attached to solid support including beads, and be included in units such as a kit (e.g. see pages 4-6). Moreover, Adema et al. teach that the antibody can be formulated into a pharmaceutical composition with pharmaceutically acceptable carriers and be presented in unit dosage form for parenteral administration, including subcutaneous administration and intravenous administration (e.g. see page 4 and 22-45).

As evidenced by Bost et al, antibodies can be specific and cross-react with the antigen. For example, antibodies which "cross-react" with IL-2 and HIV envelope protein, but establish that the binding of each protein is due to the presence of a homologous sequence in each protein in which 4 of 6 residues were identical (see entire document, but especially the Abstract and Discussion). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (e.g., "Results, page 579).

As further evidenced by Bendayan, the specific reactivity of a monoclonal antibody can be highly specific yet cross-react with antigens from different species or even distinct proteins not related to the original antigen (page 886, last paragraph).

Consequently, it was well known in the art at the time the invention was made that antibody binding of distinct proteins was indeed specific. Therefore, the reference antibody to SEQ ID NO:2 is specific to the instant polypeptide with SEQ ID NO:6."

Applicant's arguments, submitted on April 2, 2010, have been fully considered but have not been found persuasive.

Applicant argues that the claims have been amended to recite "an antigen-antibody complex". Applicant argues Adema et al. does not disclose a polypeptide consisting of the sequence of SEQ DI NO:6. Thus, Adema et al. would not anticipate the instant claims requiring an antigen-antibody complex comprising antibody and SEQ ID NO:6 or residues 1-210 of SEQ ID NO:6.

This is not found persuasive for following reasons:

Contrary to applicant's assertion that Adema et al. does not teach SEQ ID NO:6, it is again noted that there is a high degree of sequence homology between the prior art polypeptide of FDF03 of SEQ ID NO:2 and instant FDF03-S1 consisting of SEQ ID NO:6, especially in region spanning residues 1-210 (e.g. see sequence alignment attached to this Office Action), as such, monoclonal antibody that binds to the prior art SEQ ID NO:2 would inherently bind shared regions of sequence identity of the instant polypeptide FDF03-S1 of SEQ ID NO:6 including residues 1-210.

Further, Adema et al. teach immunoassays using said antibodies including monoclonal antibody or antigen-binding fragment thereof for detecting FDF03 antigen in the monocytes (the same cell the instant FDF03-S1 is found), and since the prior art antibody would cross-react with the instant FDF03-S1 for reasons of record, it is reasonable to conclude that the prior art antibody would form complex with the FDF03 of the prior art as well as the instant FDF03-S1

including in regions 1-210 (having high degree sequence homology to the FDF03) in immunoassays using monocytes (e.g. see pages 25-26).

Thus, applicant's arguments have not been found persuasive.

10. Claim 7 and newly added claim 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Escobedo et al. (US 2002/0076761, reference of record) for reasons of record.

The prior Office Action states:

"Escobedo et al. teach and claim a secreted protein having amino acid sequence of SEQ ID NO:21 wherein residues 65-291 of the SEQ ID NO:21 is 100% identical to the instant SEQ ID NO:6 (see claims 1-4 and the attached sequence alignment). Escobedo et al. further teach an antibody or fragment there of that binds SEQ ID NO:21 (e.g. see claim 5 and paragraphs [0081]-[0082]).

Given that the regions of the prior art protein and the instant SEQ ID NO:6 are 100% identical as discussed above, the prior art antibody would specifically bind the instant SEQ ID NO:6.

Regarding the recited "wherein said antibody or fragment thereof is in complex with said DFD03-S1 polypeptide", it is once again noted that such recitation does not alter the structure of the claimed antibody. Claim scope is not limited by the wherein clause that does not limit a claim to a particular structure. See MPEP 2111.04. Here, given that the claimed antibody and the prior art antibody are identical or substantially identical in structure, the prior art antibody would inherently capable of being in complex with FDF03-S1 polypeptide that is 80.4% identical in amino acid sequence of the prior art FDF03 polypeptide with SEQ ID NO:2. Applicant has not provided any objective evidence to show that the claimed antibody is structurally different from the prior art antibody.

Therefore, the reference teachings anticipate the claimed invention."

Applicant's arguments filed on April 2, 2010, have been fully considered but have not been found persuasive.

Applicant argues that the claims have been amended to recite "an antigen-antibody complex". Applicant argues Escobedo et al. do not teach SEQ ID NO:6 or residues 1-210 of SEQ ID NO:6. Thus, applicant asserts that the prior art would not anticipate the claimed invention.

This is not found persuasive for following reasons:

Contrary to applicant's assertion that Escobedo et al. do not teach SEQ ID NO:6, it is noted the prior art does teach SEQ ID NO:21 that is 100% identical to the instant SEQ ID NO:6. Thus, the prior art teaches the instant SEQ ID NO:6 and residues 1-210 of the SEQ ID NO:6 under a different name (SEQ ID NO:21). The prior art further teach an antibody that binds the mature polypeptide and that the antibody can be used for immunoassays including immuoprecipitating the desired protein (e.g. see paragraph [0081] on page 6). Thus, the prior art teachings would encompass an antibody-antibody immunocomplex that would read on the instant claims 7 and 32.

Therefore, applicant's arguments have not been found persuasive.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 7, 9, 18, 25, and newly added claims 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Escobedo et al. (US 2002/0076761) in view of Harlow et al. (Antibodies. A Laboratory Manual. 1988, pages 139-147 and 626-630) and Campbell

(Monoclonal Antibody Technology. 1985 Published by Elsevier Science Publishers. Chapter I, pages 1-32, reference of record) for reasons of record.

The prior Office Action states:

"*The teachings of Escobedo et al. have been discussed, supra.*

The reference teachings differ from the claimed invention by not describing monoclonal antibody or antibody fragment, per se.

However, methods of making monoclonal antibody and fragment thereof and the advantage of using them in various immunoassays were well known in the art at the time the invention was made. For example, Harlow et al. teach that monoclonal antibodies can be made using hybridoma technique and that the advantages of monoclonal antibodies include high specificity in binding, homogeneity, and their ability to be produced in unlimited quantities (see entire document, particularly pages 141-147). Further, Harlow et al. teach that the use of intact antibody in some immunochemical techniques can cause certain problems such as binding to Fc receptors and using antigen binding fragment, e.g. Fab, can overcome these problems; Harlow et al. teach methods of preparing antibody fragments (e.g. see pages 626-633). Campbell teaches methods of making antibodies and the advantages of using antibodies e.g. monoclonal antibody in basic research, diagnostics and therapeutic uses (see entire document, particularly pages 2-23). Further, Campbell teaches that it is customary now for any group working on macromolecule to both clone the genes coding for it and make monoclonal antibodies to it, sometimes without a clear objective for their application (e.g. see page28). Escobedo et al. clearly teach that polypeptide having amino acid sequence of SEQ ID NO:21 and one of skilled in the art would have been motivated to make antibody, e.g. monoclonal antibody, to SEQ ID NO:21 that is 100% identical to the instant SEQ ID NO:6.

It would thus have been obvious to the ordinary artisan at the time the invention was made to make monoclonal antibody and fragment thereof that specifically binds the prior art SEQ ID NO:21. The ordinary artisan would have been motivated to do so because antibodies against recombinant proteins can facilitate protein purification and monoclonal antibodies have the advantages of high specificity, homogeneity and can be produced in unlimited quantities. Given the teachings Escobedo et al. regarding the antibody that specifically binds SEQ ID NO:21 that is 100% identical to the instant SEQ ID NO:6, and the teachings of Harlow et al. and Campbell regarding methods of making and using monoclonal antibodies, the ordinary would have had a reasonable expectation of success of producing monoclonal antibodies or fragment thereof that binds prior art SEQ ID NO:21 and the instant SEQ ID NO:6."

Applicant's arguments have been fully considered but have not been found persuasive.

Applicant's arguments and the Examiner's rebuttal regarding the teachings of Escobedo et al. are essentially the same as discussed, supra.

Applicant further argues Harlow et al. and Campbell does not teach SEQ ID NO:6. Thus, applicant asserts that the invention should be withdrawn.

This is not found persuasive for following reasons:

In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combination of references. See MPEP 2145.

It is noted that in considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968). See MPEP 2144.01.

Furthermore, specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY); and In re Burckel 201 USPQ 67 (CCPA). In re Burckel is cited in MPEP 716.02.

Given the teachings Escobedo et al. regarding the antibody that specifically binds SEQ ID NO:21 that is 100% identical to the instant SEQ ID NO:6, and the teachings of Harlow et al. and Campbell regarding methods of making and using monoclonal antibodies, the ordinary would have had a reasonable expectation of success of producing monoclonal antibodies or fragment thereof that binds prior art SEQ ID NO:21 and the instant SEQ ID NO:6.

Therefore, applicant's arguments have not been found persuasive.

13. Conclusion: no claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chun Dahle
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TC 1644

/Maher M. Haddad/
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